

MD



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/928,146	08/10/2001	Douglas J. Daniels	BSC-008DV	6909

21323 7590 10/03/2003

TESTA, HURWITZ & THIBEAULT, LLP  
HIGH STREET TOWER  
125 HIGH STREET  
BOSTON, MA 02110

EXAMINER

QADERI, RUNA S

ART UNIT PAPER NUMBER

3737

DATE MAILED: 10/03/2003

S

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/928,146

Applicant(s)

DANIELS ET AL.

Examiner

Runa S. Qaderi

Art Unit

3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 August 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 36-55 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 36-55 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3. 6) ☐ Other:

**DETAILED ACTION**

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 36-40, 45-47, 52, 54, and 55 are rejected under 35 U.S.C. 102(b) as being anticipated by Seward et al. (US 5,345,940).

Seward teaches a method and an apparatus of providing ultrasound imaging and an interventional catheter. A device 20 has a distal end, proximal end, and a plurality of ports extending through the length of the device, Figure 1. A phased array transducer for transmitting and received echoes is provided on the distal end of the device. Access port(s) 40 is configured to receive a therapeutic device, such a catheter, medication, sensors, and any available interventional device. The patent further defines interventional procedures to include ablation, laser, cutting, occluding, etc., catheter based interventional procedures and/or tools, column 9 lines 1-10. A needle is defined as an example of the tool, column 11 lines 1-5. The interventional procedure is performed with the guidance of ultrasound imaging. Or in other words the ultrasound image directs the interventional procedure. The teaching to providing any available ultrasound imaging mode appropriate or desired for the interventional procedure encompassed displaying the depth of penetration, entire patent. The various

Art Unit: 3737

embodiments of the device 20 are shown through Figures 2-9 wherein a plurality of access ports are available to provide multiple interventional procedures, columns 7-8.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 41-44, 48, 50, and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seward et al.

Seward et al. teaches a device 20 and method of tissue intervention under ultrasound guidance. The ultrasound imaging apparatus and interventional device(s) are within the device (20). The patent teaches that the interventional procedures/tools include cutting, ablating, occluding, delivering materials, etc. The patent does not expressly recite a scalpel, forceps jaws, a snare, scissors, and an applying needle as said interventional procedure/tool. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide any available tool and/or procedure of intervention as taught by Seward et al. Furthermore although the patent does not expressly recite use of the device within the alimentary or the pulmonary lumen, it is well within the knowledge of an ordinary skilled artisan to utilize the method in any lumen necessary.

Art Unit: 3737

Claims 49 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seward et al. (US 5,325,860) in view of Green et al. (4,327,738).

Seward et al. teaches the means and method of an ultrasound guiding interventional procedure. Seward et al. does not teach further providing an additional imaging means and method into the device (20) wherein a first and second optical fiber transmits and receives spectroscopic imaging data. Green teaches combination optical and ultrasound imaging device. The optical device further defined as a plurality of optical fibers. It would have been obvious to a person of ordinary skill in the art to have additionally incorporated an optical imaging system within one of the access ports of Seward et al. because it provides a more efficient and through image of the region of interest as taught by Green et al.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

1. Ishiguro et al. (US 5,150,715) teaches an ultrasound-imaging diagnostic system.
2. Seward et al. (US 6,039,693) teaches volumetric image ultrasound transducer under fluid catheter system.
3. Seward et al. (US 5,325,860) teaches ultrasound and interventional catheter method.

Art Unit: 3737

4. Crowley (US 5,588,432) teaches a catheters for imaging, sensing electrical potentials, and ablating tissue.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Runa S. Qaderi whose telephone number is (703) 308-8155. The examiner can normally be reached on Mon-Fri 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dennis W. Ruhl can be reached on (703) 308-2262. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



RSQ



George Manuel